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10/713,511

11/14/2003

James R. Thacker

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10/16/2006

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EXAMINER

BERTRAM, ERIC D

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,511

Applicant(s)

THACKER ET AL.

Examiner

Eric D. Bertram

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-14 and 16-22 is/are rejected.
- 7) ☒ Claim(s) 5 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The amendments to the specification, specifically the submittal of an amended title, submitted on 7/31/06 are acknowledged and accepted. As a result, the objection to the specification is withdrawn.

Claim Objections

2. The amendments to overcome the objection to claim 3 are acknowledged and accepted. Therefore, the objection to claim 3 has been withdrawn.

Claim Rejections - 35 USC § 112

3. The amendments to claim 7 to overcome the 112(2) rejection are acknowledged and accepted. As a result, the 112(2) rejection of claim 7 is withdrawn.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 8-10 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hill et al. (US 5,403,356, hereinafter Hill). Hill discloses an anti-arrhythmia system and method for suppressing the onset of atrial fibrillation (Col. 1, lines 63-64). Hill discloses circuitry 122, 124 for detecting the cardiac cycle of a target atrium, which in this case is the right atrium of the heart (see figures 1 and 2). In response to an atrial depolarization detected by the circuitry, pulse generator outputs 110 and 112 deliver

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timed stimulation through electrodes 114, 116, 118 and 120 in order to suppress the onset of atrial fibrillation (Col. 4, lines 45-50).

6. Regarding claims 9, 10 and 17, Hill discloses delivering multiple pulses concurrently to the target atrium during an atrial contraction (Col. 5, lines 28-33). Further, as shown in figure 3, pulse generator output 112 will deliver a train of pulses 206, 214 and 234 through electrodes 118 and 120.

7. Regarding claim 18, figure 5 appears to show that pulses 204 and 206 are not exactly concurrent in time, and thus are considered to be delivered sequentially, with 204 delivered slightly before 206.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-3, 6, 7 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mower (US 6,178,351) in view of Hill. Mower discloses a cardiac pace and arrhythmia suppression system and method including detection circuitry for sensing atrial fibrillation in a heart by monitoring P-waves (atrial contractions) in the cardiac cycle (Col. 8, lines 20-34). Mower further describes attaching two electrodes 106 and 108 to a target atrium, with each electrode controlled by an independent stimulus generator in response to sensed atrial fibrillation (Col. 6, lines 15-30).

Furthermore, Mower discloses that after the atrial fibrillation is terminated, Mower then deactivates delivery of stimulus through all of the electrodes (Col. 9, lines 44-58).

However, Mower does not disclose placing the system in an atrial fibrillation suppression mode. Attention is directed to the secondary reference of Hill, which, as described above, discloses an atrial fibrillation suppression mode that delivers multiple pulses to a target atrium during the same atrial contraction. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system and method of Mower by adding the mode as taught by Hill in order

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to prevent the further occurrence of atrial fibrillation once it has been terminated so that the patient is as safe as possible by limiting the occurrences of AF.

12. Regarding claims 2, 3, 6, 12 and 13, Hill discloses delivering multiple pulses concurrently to the target atrium during an atrial contraction (Col. 5, lines 28-33). Also, as shown in figure 3, pulse generator output 112 will deliver a train of pulses 206, 214 and 234 through electrodes 118 and 120. Furthermore, figure 5 appears to show that pulses 204 and 206 are not exactly concurrent in time, and thus are considered to be delivered sequentially, with 204 delivered slightly before 206.

13. Regarding claim 7, the Examiner takes Official Notice that the use of biphasic pulses in the art of cardiac pacing is notoriously old and well known in the art. Biphasic pulses are used in order to balance the charge delivered to the tissue, thus preventing damage to the tissue.

14. Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mower in view of Hill, and further in view of Schloss et al. (US 6,292,694, hereinafter Schloss). Mower, as modified above, discloses the applicant's basic invention with the exception of delivering pulses to suppress the onset of atrial fibrillation that are timed to induce a faster than native atrial contractions. Attention is directed to the secondary reference of Schloss, which discloses the use of atrial overdrive pacing pulses in order to prevent atrial fibrillation (Col. 9, lines 1-4). As is known in the art, overdrive pacing results in atrial contractions that are "overdriven", and as a result contract faster than a native contraction. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system and method of Mower by

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adding overdrive pacing as taught by Schloss since this is a known pacing technique for preventing atrial fibrillation.

15. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hill in view of Schloss. Hill, as described above, discloses the applicant's basic invention with the exception of delivering pulses to suppress the onset of atrial fibrillation that are timed to induce a faster than native atrial contractions. Attention is directed to the secondary reference of Schloss, which discloses the use of atrial overdrive pacing pulses in order to prevent atrial fibrillation (Col. 9, lines 1-4). As is known in the art, overdrive pacing results in atrial contractions that are "overdriven", and as a result contract faster than a native contraction. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system and method of Hill by adding overdrive pacing as taught by Schloss since this is a known pacing technique for preventing atrial fibrillation.

16. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill in view of Warman et al. (US 2004/0088010, hereinafter Warman). Hill, as described above, discloses the applicant's basic invention, including providing at least two electrodes to a target atrium for sensing and independent delivery of stimuli. However, Hill does not disclose delivering pulses to suppress the onset of atrial fibrillation that are timed to induce a faster than native atrial contractions and forestall initiation of conduction circus motions. Attention is directed to the secondary reference of Warman, which discloses that overdrive pacing is effective in disrupting circus conduction and terminating atrial fibrillation (par. 0004). As is known in the art,

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overdrive pacing results in atrial contractions that are "overdriven", and as a result contract faster than a native contraction. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system and method of Hill by adding overdrive pacing as taught by Warman since this is a known pacing technique for preventing atrial fibrillation.

Allowable Subject Matter

17. Claims 5 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mehra (US 5,683,429) discloses a pacing method for preventing the onset of atrial fibrillation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 9-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766

EDB



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766